potential dangers associated with a risk management culture, and continue to encourage measures to promote autonomy and independence in older people.[12]

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Competing interests: None declared.

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Extending CONSORT to include cluster trials

Welcome extension will help to understand trials better and reduce bias

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Anyone who has tried to appraise a randomised controlled trial critically will be aware of the frustration that arises when a key piece of information is missing. To understand the results of a randomised controlled trial a reader must understand its design, conduct, analysis, and interpretation. That goal can be achieved only through complete transparency from authors. The original and revised CONSORT (consolidated standards of reporting trials) statements were designed to help authors improve reporting by using a checklist and flow diagram and have been well cited.[1] These have now been extended to include cluster trials (p 702).[2] Cluster trials randomise interventions to groups of patients rather than to individual patients and have their own problems. Using the extended CONSORT statement should help reduce bias and help readers to understand a cluster trial's conduct and to assess the validity of its results.

A website provided by the Medical Research Council gives guidelines for the design and analysis of cluster trials.[3] These trials are particularly useful in general practice where the cluster is the general practitioner or the practice.[4] For example, in the Diabetes Care from Diagnosis Trial, general practitioners were randomised to be trained in patient centred care or not.[5] All patients under the care of one general practitioner receive the same treatment and so cannot be considered to be independent items. One of the main reasons for conducting cluster trials is fear of contamination, whereby patients used as controls are exposed to the intervention. For example, it would be difficult for a general practitioner to switch from a patient centred approach to a more paternalistic approach between successive patients. Patients in one practice may discuss what their general practitioner has given them, and patients used as controls may demand the same treatment as those given the intervention.

The main problem associated with their design, conduct, analysis, and interpretation, compared with individually randomised trials, is that two different units of measurement—the cluster and the patient—are used. Each needs to be reported carefully. The key statistic is the intracluster correlation coefficient, which is the ratio of the between cluster variation of the outcome variable to the total variation. The startling fact is that even with apparently low values of the intracluster correlation coefficient, such as 0.05 (which is commonly found in general practice trials), when there are reasonable numbers of patients in each cluster (say 20), then the usual methods of analysis, which fail to take into account clustering, can seriously underestimate the standard error of treatment effects and so provide spuriously narrow confidence intervals. Compared with individually randomised trials cluster trials therefore are inefficient in terms of power for a given effect size and sample size. Other problems are that randomisation has to occur at the start of the trial, and blinding these trials is more difficult, thus increasing the potential for recruitment biases. Cluster leaders have to consent to the trial on behalf of the potential cluster members, which raises ethical issues. Several surveys have highlighted problems in all these areas in the past, although there is evidence that more recent trials are better reported, perhaps because of recent efforts by medical statisticians to make the research community aware of the difficulties of cluster randomised trials.[6 7]

The extension to cluster trials is timely since the number of trials reporting a cluster design has risen exponentially since 1997. That the revised statement should appear in the *BMJ* is fitting, since a recent review of cluster trials published since 1997 in the *Lancet*, *New England Journal of Medicine*, and the *BMJ*, showed that 24 of the 36 trials found had appeared in the *BMJ*.[7]

The checklist items relate to the content of the title, abstract, introduction, methods, results, and discussion. Similar to the statement for individually randomised trials the checklist includes 22 items, chosen to reflect

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important aspects of cluster trials. A failure to report an item is important because it may be associated with biased estimates of treatment effect or because the information is essential to judge the reliability or relevance of the findings. The flow diagram emphasises that the important unit is the cluster, and reporting of how both the cluster as well as the individuals progress through the trial is important. On a more pragmatic level, hopefully, investigators reading the checklist will be guided as to the correct way to calculate the required sample size, to randomise to minimise bias, to analyse the data at the end, and to report the intracluster correlation coefficient.

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Diagnosis of stroke on neuroimaging

"Scan all immediately" strategy improves outcomes and reduces costs

Stroke is the clinical syndrome of rapid onset of focal, or sometimes global, cerebral deficit with a vascular cause, lasting more than 24 hours or leading to death.[1] Eighty per cent of strokes are ischaemic, 15% are due to intracerebral haemorrhage, and 5% to subarachnoid haemorrhage. Correct diagnosis is important because treatments for ischaemic stroke[2] may be contraindicated in intracerebral haemorrhage.[3] The diagnosis requires imaging of the brain.[4] But which imaging—computed tomography or magnetic resonance—how quickly should it be done, should this include imaging cerebral blood flow, and what is the most cost effective approach?

The average general hospital (catchment population 250 000-500 000) will see two to three patients with stroke per day. Many patients have poor airway control, are confused, or are unable to communicate. Routine imaging for most patients must therefore be quick (speed is of the essence for patients, salvaging their brain, and for the radiology department), practical, readily available, and yield the key diagnostic information. There is, however, no imaging technique that does all of these perfectly.

Computed tomography scanning is practical, quick (a few minutes to scan a brain), widely available, and easy to use in ill patients. It accurately identifies intracerebral haemorrhage as soon as it has occurred, but the technique has limitations. Intracerebral haemorrhage will be misinterpreted as ischaemic stroke if computed tomography is not done within 10-14 days after stroke.[5] Delays in seeking medical attention or poor access to computed tomography for stroke will result in failure to identify up to three quarters of intracerebral haemorrhage[5] and may lead to inappropriate treatment (for example, aspirin or carotid endarterectomy) for many.

Computed tomography scanning shows positive features of ischaemic stroke in many patients with severe and moderate strokes scanned two to seven days after the event, but early signs of ischaemia (within three to six hours) are difficult to recognise.[6] Many patients with mild stroke never develop a visible infarct on computed tomography, no matter when they are scanned.[7] The clinical diagnosis of stroke can be difficult in the first few hours after onset, so many doctors would value a diagnostic test not only to exclude intracerebral haemorrhage or tumour (found in 4-20% initially diagnosed as "stroke"), but also positively to confirm ischaemic stroke. The subtle early signs of infarction on computed tomography include grey matter becoming isodense with white matter, loss of the basal ganglia and insular ribbon outlines, a little swelling reducing the visibility of sulci or ventricles, and a hyperdense artery (figure). If any of these signs are important for making decisions regarding treatment—for example, deciding whether or not to give thrombolysis[8]—then improving their recognition is vital. The acute cerebral CT evaluation of stroke study (ACCESS), in which as many doctors and radiologists as possible worldwide interpret typical computed tomography scans of stroke over the internet, aims to improve recognition of early signs of infarction (please try your hand at www.neuroimage.co.uk—completion carries five category 1 credits for continuing medical education).

The quest for a positive diagnosis of ischaemic stroke fuelled the use of magnetic resonance imaging—for example, diffusion weighted imaging, which shows early ischaemic changes as a bright white lesion ("lightbulb"). More ischaemic strokes show up on diffusion weighted imaging than on computed tomography or conventional magnetic resonance imaging in the first few hours[9] and weeks later, which makes this technique especially useful for positive identification of an ischaemic stroke in patients presenting up to eight weeks after stroke.[10] Previous

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